

Department of Pesticide Regulation



California Notice 2005-02

SEMIANNUAL REPORT SUMMARIZING THE REEVALUATION STATUS OF PESTICIDE PRODUCTS DURING THE PERIOD OF July 1, 2004 THROUGH December 31, 2004

California regulations require the Department of Pesticide Regulation (DPR) to investigate reports of possible adverse effects to people or the environment resulting from the use of pesticides. If a significant adverse impact occurred or is likely to occur, the regulations require DPR to reevaluate the registration of the pesticide.

Title 3, California Code of Regulations (CCR), section 6221, specifies the factors under which DPR may initiate a reevaluation: (a) public or worker health hazard, (b) environmental contamination, (c) residue over tolerance, (d) fish or wildlife hazard, (e) lack of efficacy, (f) undesirable phytotoxicity, (g) hazardous packaging, (h) inadequate labeling, (i) disruption of the implementation or conduct of pest management, (j) other information suggesting a significant adverse effect, (k) availability of an effective and feasible alternative material or procedure that is demonstrably less destructive to the environment, and (l) discovery that data upon which a registration was issued is false, misleading, or incomplete. Often, ongoing DPR reviews trigger a reevaluation. Reevaluation triggers also include State and county pesticide use surveillance and illness investigations, pesticide residue sample analyses, environmental monitoring activities, and information from other state or federal agencies.

When a pesticide enters the reevaluation process, DPR reviews existing data. DPR requires registrants to provide additional data to determine the nature or the extent of the potential hazard or identify appropriate mitigation measures, if needed.

DPR concludes reevaluations in a number of different ways. If the data demonstrate that use of the pesticide presents no significant adverse effects, DPR concludes the reevaluation without additional mitigation measures. If additional mitigation measures are necessary, DPR places appropriate restrictions upon the use of the pesticide to mitigate the potential adverse effect. If the adverse impact cannot be mitigated, DPR cancels or suspends the registration of the pesticide product(s).

This report complies with the requirements of CCR section 6225. CCR section 6225 requires DPR to prepare a semiannual report describing pesticides evaluated, under reevaluation, or for which factual or scientific information was received, but no reevaluation was initiated. The report contains two sections:

I. Formal Reevaluation - initiated when an investigation indicates a significant adverse impact has occurred or is likely to occur (page - 2); and



II. Preliminary Investigations (Evaluations) - products or active ingredients for which DPR receives possible adverse factual or scientific information, but no reevaluation has been initiated (page - 8).

I. FORMAL REEVALUATION

Undertaken when investigations indicate that a significant adverse impact has occurred or is likely to occur.

BRODIFACOUM - 35 Products

Pesticide products containing brodifacoum are registered in California for the control of rats and mice in residential, industrial, commercial, agricultural, and public buildings. Registrants formulate the product with a grain-based bait in pellets, mini—pellets, and wax blocks. On December 30, 1999, at the request of the Department of Fish and Game (DFG), DPR placed pesticide products containing brodifacoum into reevaluation. DFG expressed concern that California's wildlife are exposed and may be adversely affected by currently registered uses of the anticoagulant rodenticide brodifacoum.

DPR and DFG staff met with representatives of the Rodenticide Registrant Task Force in April 2001. At that meeting, DPR agreed to review additional information submitted by the registrants. DPR's biologist reviewed all data; slides, scientific journal articles, and correspondence submitted by the Rodenticide Registrant Task Force and other brodifacoum registrants. In October 2001, DPR learned that the U.S. Environmental Protection Agency (U.S. EPA) was completing a final draft of its ecological assessment of brodifacoum and several other rodenticides. DPR decided to wait for the completion of U.S. EPA's assessment. In January of 2003, U.S. EPA released its preliminary comparative ecological assessment for nine rodenticides, including brodifacoum, for a 60-day public comment period. U.S. EPA's preliminary assessment indicates that of the nine rodenticides studied, brodifacoum appears to pose the greatest potential overall risk to birds and nontarget mammals.

Based on comments received, U.S. EPA revised its Comparative Ecological Risk Assessment on Rodenticides in July 2004. U.S. EPA's revised assessment can be found at the following web address: http://docket.epa.gov/ under Docket ID number OPP-2004-0033. The deadline for public comment on the revised assessment is January 21, 2005. On December 1, 2004, Sygenta Crop Protection, Inc. presented DPR staff with the results of an ecological risk assessment conducted by Syngenta. DPR plans to delay further processing of the brodifacoum reevaluation pending U.S. EPA's proposed action.

CHLOROPICRIN – 56 Products

Chloropicrin is a colorless liquid that volatilizes readily when released into the atmosphere. Chloropicrin has been used as an insecticide since 1917 and a soil fumigant since 1920. As a space and soil fumigant, chloropicrin controls nematodes, bacteria, fungi, insects, and weeds. Chloropicrin can be used alone or in combination with other fumigants such as telone or methyl bromide. Because of its strong odor, small amounts of chloropicrin are added to methyl bromide and other fumigant applications as a warning agent.

Data submitted to DPR under the Birth Defect Prevention Act indicate that chloropicrin has the potential to cause adverse health effects at low doses. The National Institute for Occupational Safety and Health (NIOSH) set an 8-hour time-weighted average (TWA) of 0.1 parts per million (ppm) as the reference exposure limit (REL) for workers exposed to chloropicrin. The NIOSH standard of 0.1 ppm was recommended primarily for the prevention of eye irritation in humans.

Air monitoring data submitted by the Chloropicrin Manufacturers Task Force (CMTF) indicate that the air levels of chloropicrin at some distances from treated greenhouses or fields could exceed the NIOSH standard. In the CMTF studies, off-site movement of chloropicrin was monitored during and after soil fumigation using four application methods in three states. At the Arizona applications, considered to have meteorological conditions most comparable to California, 4 of the 16 monitoring stations located 180 feet from the treated fields had chloropicrin levels at or exceeding the NIOSH standard. The highest level monitored was around 1,700 $\mu g/m^3$ (i.e., 0.25 ppm). The flux or emissions of chloropicrin was also measured using the aerodynamic method. At the Arizona sites, the flux ranged from 114 to 222 $\mu g/m^2$ /sec, or 12 to 25 percent of the chloropicrin applied during the highest 6-hour period. In addition, depending upon the aeration system used, the ambient air concentrations of chloropicrin near treated greenhouses could increase significantly following the required ventilation operation. A typical aeration would involve venting the air in the greenhouse directly out to the exterior environment.

Pursuant to this reevaluation, DPR is requiring chloropicrin registrants to conduct and submit the results of various worker exposure and air quality monitoring studies from field and greenhouse applications. In September 2002, CMTF submitted protocols for a worker exposure and air monitoring study. DPR reviewed and approved the protocols in December 2002. In May 2003, DPR staff met with CMTF to discuss the greenhouse monitoring study. DPR met with CMTF on August 12, 2004 to discuss the required studies. DPR received the final results of the worker exposure and air monitoring studies on December 8, 2004. The studies are under review.

CHLORPYRIFOS – 39 Products

The pesticide active ingredient chlorpyrifos is an insecticide registered for use on a variety of agricultural crops, turf, and for control of various insects indoors and outdoors. Chlorpyrifos is formulated as dust, wettable powders, emulsifiable concentrate, concentrates and ready-to-use solutions.

In March 2004, DPR placed all agricultural use (includes turf uses) products containing chlorpyrifos into reevaluation. The basis for the reevaluation is monitoring data collected by the Central Valley Regional Water Qualify Control Board. The monitoring data showed chlorpyrifos levels in the rivers and tributaries of the San Joaquin Valley, the Sacramento/San Joaquin Delta, and Monterey County tributaries that exceeded the Department of Fish and Game's (DFG's) water quality objectives (WQO) for aquatic invertebrates.

Pursuant to this reevaluation, chlorpyrifos registrants are required to: (1) identify the processes by which chlorpyrifos pesticide products are contributing to detections of chlorpyrifos in surface water at levels that exceed DFG's WQOs; and (2) identify mitigation strategies that have been shown to reduce or eliminate chlorpyrifos residues in surface water. The basic manufacturer of chlorpyrifos responded to the reevaluation with the submission of data and information. DPR reviewed the submitted information, and agreed with Dow's assessment of the modes of transport of chlorpyrifos residues to surface water. The next step in the reevaluation is the identification of mitigation strategies that will reduce or eliminate chlorpyrifos residues in surface water when used under California conditions for all major agricultural uses. Each proposed mitigation measure must be supported by scientific studies.

CYFLUTHRIN -55 Products

The pesticide active ingredient cyfluthrin is a nonsystemic pyrethroid insecticide registered for use on numerous field, fruit, and vegetable crops, including citrus. In addition, DPR registers pesticide products containing cyfluthrin for use on lawns and ornamental plants, animals, and around industrial, institutional, agricultural, and household structures.

DPR initiated the reevaluation on May 8, 1998, based on its investigation of a May 1997 outbreak of respiratory irritation reported among orange harvesters exposed to residues of cyfluthrin in Tulare County and other pesticide illness reports related to cyfluthrin. As a part of the investigation of the Tulare County incident, DPR's Worker Health and Safety Branch conducted two separate inhalation-monitoring studies in orange groves during orange harvest. DPR determined that since dust and pollen are a part of the normal working environment, something different in the work environment led to the workers' respiratory irritation symptoms. DPR believes that the application of cyfluthrin to the citrus groves close to harvest led to the respiratory symptoms experienced. DPR compiled the results of its monitoring study in "Health and Safety Report, HS - 1765."

In mid-September 1998, the basic manufacturer of cyfluthrin submitted the results of several studies and journal articles concerning the respiratory irritation of cyfluthrin. On October 29, 1998, DPR met with the basic manufacturer to discuss the cyfluthrin reevaluation. At that meeting, DPR agreed to review the submitted studies and journal articles before deciding whether to require additional data. DPR reviewed the results of three studies regarding respiratory irritation. In the mouse study, a NOEL of 5.4 mg/m³ was identified, which was based on the reduced respiratory rate noted at the 21.9 mg/m³ exposure level. In the rat study, at the lowest exposure level of 0.7 mg/m³, the respiratory rate was minimally reduced in comparison to the control animals. The author calculated a NOEL of 0.5 mg/m³. In the human study, human subjects were exposed under static conditions in which the initial exposure concentrations were reported to be 0.18 and 0.1 mg/m³ for the two exposure groups. Throat and nasal irritation was noted by 8 of the 10 subjects in both exposures. Due to several problems including the indeterminate concentration to which the subjects were exposed, a NOEL for sensory irritation could not be established. Since the rat is more sensitive than the mouse in regard to the irritating effects of cyfluthrin, the most appropriate NOEL appears to be the 0.5 mg/m³ derived from the rat study.

On August 16, 2001, DPR again met with the basic manufacturer to discuss the reevaluation of cyfluthrin. At the meeting, DPR agreed to review some additional new data before requiring further tests. In October 2001, the basic manufacturer submitted: (1) two worker exposure studies regarding hand harvesting of oranges and sweet corn; (2) four indoor exposure studies; and (3) a study entitled "Study on the RD₅₀ Determination in Rats." Based on these data, DPR determined that no further structural monitoring data are required. However, a worker exposure study of hand harvesting sweet corn is still required. In September 2002, the basic manufacturer of cyfluthrin submitted a protocol for a sweet corn exposure study. DPR staff reviewed and approved the protocol in October 2002. The first phase of the corn exposure study was conducted in the spring of 2003. The second phase of the study took place in the fall of 2003. The results of the study were submitted to DPR in October 2004. DPR's anticipates completing its risk assessment of cyfluthrin in 2005.

DIAZINON - 20 Products

The pesticide active ingredient diazinon is an insecticide registered for use on a variety of agricultural crops and livestock, on turf and for control of various insects indoors and outdoors (about 80% of usage). Diazinon is formulated as dust, granules, wettable powders, seed dressings, emulsifiable solutions, impregnated materials, encapsulated materials, concentrates and ready-to-use solutions.

DPR initiated the reevaluation of diazinon products labeled for use as dormant sprays based on monitoring studies conducted between 1991 and 2001 by the U.S. Geological Survey, Dow Agrosciences, DPR, the California Regional Water Quality Control Board, Central Valley Region, and the State Water Resources Control Board. These studies demonstrate the

presence of diazinon in surface waters of the Sacramento and San Joaquin Valleys at levels that exceed DFG's water quality criteria (WQC), especially during the dormant spray season.

To mitigate off-site movement of diazinon residues, diazinon registrants developed supplemental labeling for dormant spray diazinon products. The supplemental labeling adds mitigation measures, such as restricting application to ground equipment only, prohibiting application within 100 feet upslope of "sensitive aquatic sites," and prohibiting application to orchards when soil moisture is at field capacity, or when a storm event is likely. The supplemental labeling has been approved for use in California for fifteen of the currently registered diazinon products. The remaining products are waiting for U.S. EPA approval of the amended labeling.

In May 2004, the registrant submitted an update on various studies that are planned or in progress, and which are intended to indicate whether the new mitigation measures will be effective. In November 2004, DPR staff met with the registrant to discuss revisions to study protocols. DPR expects the studies to be conducted in the first quarter of 2005.

METHYL BROMIDE - 50 Products

Methyl bromide is a colorless and odorless gas that has been widely used since the 1940s as a preplant soil fumigant for controlling nematodes, plant pathogens, weeds, and insects. After harvest, it is used to protect crops from pest damage during storage and transportation. Methyl bromide is also used to eradicate wood-destroying pests in homes and other structures, and to control pests in mills, ships, railroad cars, and other transportation vehicles.

Since the early 1990s, DPR has focused considerable attention on ensuring the safe use of the fumigant methyl bromide. The Air Resources Board monitored during the 2000 methyl bromide use season to measure ambient air concentrations and ascertain whether they posed a threat to public health. Data indicate that short-term levels of methyl bromide were well within acceptable limits. However, data also indicate that ambient air concentrations in a number of locations exceeded DPR's target exposure level for seasonal (six- to eight-week) exposures. DPR has determined that in certain high-use areas, the use of methyl bromide may cause an adverse impact. On June 26, 2001, DPR placed all products containing methyl bromide and allowing field fumigation into reevaluation based on the results of the 2000 monitoring data.

To determine the extent of seasonal exposure to methyl bromide in 2001, DPR required registrants to conduct ambient air quality monitoring in the Camarillo/Oxnard area of Ventura County and Santa Maria area of Santa Barbara County. The Alliance of the Methyl Bromide Industry (AMBI) completed its ambient air monitoring in October 2001 and submitted a final report in April 2002.

For 2002, DPR required methyl bromide registrants to conduct and submit the results of ambient air quality monitoring in Monterey/Santa Cruz and Ventura counties. Monitoring in Ventura County was completed in August 2002. Monitoring in Monterey and Santa Cruz counties was completed in October 2002. The Alliance submitted the final results of the 2002 studies in April 2003, and DPR completed its review of the data in June 2003.

Effective January 14, 2001, DPR adopted permanent methyl bromide field fumigation regulations to mitigate possible acute exposures to methyl bromide, and then adopted amendments to these regulations on April 8, 2002. However, the regulations were voided by a court decision (Ventura County Agricultural Association vs. DPR) on the grounds that DPR had not adequately consulted with the California Department of Food and Agriculture prior to noticing the regulations. In order to maintain continuity and to ensure continued protection of the health and safety of workers and the public when methyl bromide is used for field fumigation, DPR filed emergency regulations to repeal and readopt these regulations. During the process to permanently adopt these regulations, DPR determined that additional mitigation measures were necessary and proposed an additional regulatory level to protect the public and agricultural employees from possible subchronic methyl bromide exposure hazards. On November 3, 2004, the Office of Administrative Law approved the methyl bromide field fumigation regulations.

PESTICIDE PRODUCTS CONTAINING ORYZALIN AND INTENDED FOR USE AROUND BEARING ALMOND TREES – 2 Products

DPR initiated this reevaluation based on the results of almond residue data currently on file with DPR. One company submitted an interim report of three "magnitude of residue trials" in and on almonds. In each of the three residue trials, the soil surface of the orchard floor was treated twice at the maximum application rate of six pounds of active ingredient per acre, with approximately two and one-half months between applications. Once ripe, the almonds were harvested by knocking/shaking them from the tree to the soil surface below. This is the commercial practice for harvesting almonds. The almonds were gathered and almond samples collected 39 to 70 days after the final oryzalin application. The almond nutmeat and hull samples were analyzed separately for oryzalin residues. The U.S. EPA established tolerance for oryzalin residues on almond nutmeat and hulls is 0.05 parts per million (ppm), which is the limit of quantification (LOQ) for the analytical method. Interim results indicate that no oryzalin residues at greater than, or equal to, the LOQ were detected on any of the almond nutmeat samples. However, analysis of the almond hulls detected oryzalin residues ranging from less than 0.05 ppm to 0.522 ppm. Almond hulls are sold for use as animal feed. This raises the concern that the legal use of oryzalin may result in oryzalin residues in animal feed that exceed the established tolerance.

Other oryzalin residue studies, already on file with DPR, include four almond trials conducted from 1971 to 1973. In the trials, the soil surface of an almond orchard was treated

with oryzalin one time at an application rate of three pounds of active ingredient per acre. Almond samples were harvested five to seven months after the application, and almond meats, shells and hulls were analyzed for oryzalin residues. The study results indicate that no oryzalin residues were detected in any sample. However, the study report does not indicate how the almond samples were harvested. If the almonds were not knocked to the ground before harvest, it is unlikely that the almond hulls would pick up any oryzalin residues.

The first company's data showed residues on almond hulls that clearly exceed the established tolerance, and because it is unclear how the almonds in the other studies were harvested, DPR placed all agricultural use oryzalin products in reevaluation and required the registrants to conduct a new almond residue study. The almonds were required to be treated at the maximum rate allowed by the product label, and harvested in the same manner as is done commercially in California. DPR reviewed the results of the new almond residue studies, and found that out of eight trials, no over-tolerances were found on either almond nutmeat or hulls. Oryzalin residues on all of the samples were either at or below the established tolerance of 0.05 ppm. The submitted data indicate that the treatment of almond orchards using normal commercial practices is not likely to result in oryzalin over-tolerances on either almond nutmeat or almond hulls. Therefore, no additional mitigation measures are necessary and the reevaluation was concluded on September 22, 2004.

II. PRELIMINARY INVESTIGATIONS (EVALUATIONS)

DPR conducts preliminary investigations on products for which DPR or other State or county agencies have identified possible hazards. As a result of evaluation, the investigations may lead to formal reevaluation.

No current investigations.

For more information, please contact Ms. Ann Prichard, Senior Environmental Research Specialist in the Pesticide Registration Branch, by e-mail at <aprichard@cdpr.ca.gov> or by telephone at (916) 324-3931.

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Date

cc: Ms. Ann Prichard